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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,861	03/31/2004	Edward Vaquero	P03505	5583
23702 7590 05/23/2008 Bausch & Lomb Incorporated One Bausch & Lomb Place Rochester, NY 14604-2701				
EXAMINER				
NGUYEN, TUAN VAN				
ART UNIT		PAPER NUMBER		
3731				
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05/23/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/813,861

Applicant(s)

VAQUERO, EDWARD

Examiner

TUAN V. NGUYEN

Art Unit

3731

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-15 and 18-24 is/are pending in the application.
- 4a) Of the above claim(s) 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-15 and 18-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S5108)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

1. In previous Office action, claims 13-22 were pending and they were examined and rejected.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after the final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 10, 2008 has been entered.

Response to Amendment

3. According to the amendment filed on March 10, 2008, claims 23 and 24 are new and claims 16-17 have been canceled. Accordingly, claims 13-15 and 18-24 are pending in this present application.
4. According to the amendment, claim 16 has been canceled, therefore, the rejection under 35 USC § 112 in previous Office action is moot.
5. Applicant's arguments filed on March 10, 2008 with respect to the rejections under 35 USC § 102 and 103 have been fully considered but they are moot in view of the new grounds of rejection.

Election/Restrictions

6. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I: Claims 13-16 and 18-23, drawn to an IOL injector, classified in class 606, subclass 107.

Group II: Claim 24, drawn to method for insertion of an IOL, classified in class 128 subclass 898.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process (MPEP § 806.05(e)). In this case the apparatus as claimed can be practiced by another and materially different process such as for injecting a marker to mark a tissue inside a human body.

7. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because on or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

- (c) the inventions required a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
 - (d) the prior art applicable to one invention would not likely be applicable to another invention;
 - (e) the inventions are likely to raise difference non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.
8. Applicant is advised that the reply to this requirement to be complete must include
- (i) an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the election invention.
9. The election of an invention may be made with or without traverse. To reverse a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144.
10. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the invention.

11. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.
12. A telephone call was made to Mr. Jeffrey B. Powers (Reg. No. 45,021) on May 15, 2008 to discuss the restriction requirement. The result was a provisional election was made without traverse to prosecute the invention of Group I, claims 13-15 and 18-23. Claim 24 has been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Affirmation of this election must be made by applicant in replying to this Office action.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
15. **Claims 13-15 and 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al (U.S. 6491697) in view of Brown et al (U.S. 6010510).**
16. Regarding claims 13 and 18-23, Clark discloses (Fig. 1) an injector body 22 having a first segment 103; a cannula 28, wherein the cannula includes a tip 105 or third segment, and wherein the tip having a constant diameter; two slots 121 disposed at the distal region of the tip, and slanted face 119 located at the distal end of the tip; a lumen 107, which extends through cannula 28, is axially aligned with passage 76 of compressing station 26 or loading bay; a compressor drawer 40 extending from the loading bay 26, wherein the drawer comprises a groove 70 (Fig. 6A-6C), which is aligned with the lumen grooves 68 and 76 (col. 3, lines 50-65; col. 4, lines 55-68; col. 5, lines 58-68; and col. 6, lines 30-50). Clark discloses the invention substantially as claimed except for the cannula 28 further comprises a second segment, wherein the second segment connected to the third segment at the transition point, the transition point characterized by a discrete change in taper. However, Brown et al disclose (Fig. 4) and IOL injector comprising, among other things, a tip comprising a third segment having a constant diameter, a second segment having taper located on the outer surface and a taper located on the inner surface of bore 16. Apparently, the advantage is for compressing the IOL to fit through a small tip for easy insertion of the injector into a small incision in the

ocular tissue. Therefore, it would have been obvious to one of ordinary skill in the art to modify the cannula 28 of Clark according to the suggestion of Brown et al so that it too would have this advantage. With respect to the limitation of "at least one slot extending from the open end through the second segment and third segment". Noting that Clark et al disclose slots 121 disposed at the distal region of cannula 28, it would have been obvious to one of ordinary skill in the art to optimize the length of slots 121 to extend through the second segment to ensure that the IOL gradually return to its original shape before it is released into the eye to avoid the complication of injury to the eye or tissue near the implanted site from the energy release by IOL while it is "spring" back from the deformation configuration. Extrinsic evidence, Feingold et al (US 6056757), column 1, line 64 to column 2, line 16.

17. Regarding claim 14, Clark et al fail to disclose the specific dimension. However, it is old and well known to make the size of an insertion segment of an IOL injector as claimed in order to obtain the advantage of permitting easy insertion of the injector into the eye. It would have been obvious to so size the Clark et al IOL injector so that it too would have this advantage. Extrinsic evidence, Feingold et al (US 6056757) discloses the size of the incision in the ocular tissue necessary to implant an intraocular lens within the capsule of the eye continues to decrease with the progress of intraocular lens deformation technology (col. 1, lines 62-68).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuan V. Nguyen whose telephone number is 571-272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/T. V. N./
Examiner, Art Unit 3731
/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731